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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,901	03/26/2004	Hiraku Murayama	018961-068	7688

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EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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03/24/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/809,901	<b>Applicant(s)</b> MURAYAMA ET AL.	
	<b>Examiner</b> JEFFREY G. HOEKSTRA	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 12/31/2007, amendment(s) to the specification, and amended claim(s) 3, 4, 8, 9, and 11 is/are acknowledged. The current rejections of the claim(s) 1-4 and 7-14 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-4 and 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrasekaran (US 6,093,157) as broadly as structurally claimed.
4. For claims 1-4 and 7-14, Chandrasekaran discloses a composite guidewire (22,80,82), comprising:
- a distal end portion (the right portion of the guidewire in Figure 1), a main body portion (the left portion of the guidewire in Figure 1), and an intermediate portion (the middle portion of the guidewire in Figure 1) disposed between the distal end portion and the main body portion;
  - wherein said main body portion comprises: a center layer (34,60,78) formed of a first material comprising a NiTi based alloy (column 4 lines 3-5); a surface layer formed of a second, more rigid material comprising stainless steel (49,64) (column 2 line 59 – column 3 line 2 and column 5 lines 35-67); and (c) an intermediate layer (48)

formed of a mixture of said first and second materials (column 4 line 66 – column 5 line 10) between said center and surface layers (as best seen in Figure 5);

- wherein said main body portion has a structure in which said center layer, said intermediate layer, said surface layer are structurally disposed in this order from a center of said main body portion toward an exterior of said main body portion (as best seen in Figure 5) (column 2 line 59 – column 3 line 2);
- wherein said distal end portion is formed of said first material, and is continuous with the center layer of said main body portion (as best seen in Figures 7-8);
- wherein said intermediate portion comprises: the center layer (34,60,78) formed of the first material comprising a NiTi based alloy and an intermediate surface layer (48) formed of the mixture of said first material and said second material;
- wherein the mixture is decreased in the content of said first material toward said surface layer and increased in the content of said second material toward said surface layer such that a compositional gradually increasing gradient is formed in a radial direction (column 2 line 59 – column 3 line 2 and column 4 line 66 – column 5 line 10);
- wherein a weight ratio of the first to second material in the mixture is capable of being in the range of 1:9 to 9:1 and more specifically in the range of 3:7 to 7:3 because this ratio is inherently dependent upon material selection (as cited by Applicant, see Specification at least page 8 lines 1-4); and
- wherein said main body portion is capable of being formed by a sintered body, said sintered body having said center layer, said surface layer, and said intermediate

layer, wherein said center layer is capable of being formed by sintering a powder of said first material, said surface layer is capable of being formed by sintering a powder of said second material, and said intermediate layer is capable of being formed by sintering a powder of said mixture of said first material powder and said second material powder.

### ***Response to Arguments***

5. Applicant's arguments filed 12/31/2007 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of the claims under Chandrasekaran.

6. For independent claim 1, Applicant argues Chandrasekaran fails to disclose 1) the second material forming the surface layer is a metallic material higher in rigidity than said Ni-Ti based alloy, 2) the intermediate layer is formed of a mixture of said first material and said second material, and 3) the weight ratio of the first material to the second material in the material for forming the intermediate layer is in the range of from 1:9 to 9:1.

7. For independent claim 8, Applicant argues Chandrasekaran fails to disclose 4) a surface layer formed of a mixture of the first material forming the center layer and a second material, 5) a surface layer is decreased in a content of said first material toward an outer surface and increased in a content of said second material toward the outer surface, and 6) a surface layer having gradient physical properties in a radial direction.

8. For independent claim 9, Applicant argues Chandrasekaran fails to disclose 7) a center layer, intermediate layer, and surface layer provided in this order from a center of said main body portion toward an exterior of said main body portion, or an intermediate layer formed of a mixture of the first material forming the center layer and the second material forming the surface layer. There is also no disclosure of an intermediate layer increased stepwise or gradually in a content of said first material toward said center layer, wherein the first material is a first metallic material, said second material is a second metallic material higher in rigidity than said first metallic material, and said second metallic material is stainless steel.

9. For depending claims 13 and 14, Applicant argues Chandrasekaran fails to disclose or suggest formation of the central shaft by sintering.

10. The Examiner disagrees, maintains the rejection as broadly as structurally claimed and as reiterated above, and notes in response the following:

11. In regards to Applicant's arguments with respect to independent claim 1, the Examiner notes in response to

1) Chandrasekaran discloses a composite guidewire wherein a center layer (34,60,78) formed of a first material comprising a NiTi based alloy (column 4 lines 3-5) and a surface layer formed of a second, more rigid material comprising stainless steel (49,64) (column 2 line 59 – column 3 line 2 and column 5 lines 35-67) (as admitted by Applicant, see Specification at least page 6 lines 11-19 and page 7 lines 14-27);

2) Chandrasekaran discloses a composite guidewire wherein an intermediate layer (48) formed of a mixture of said first and second materials (column 4 line 66 – column 5 line 10) between said center and surface layers (as best seen in Figure 5), wherein said intermediate portion comprises: the center layer (34,60,78) formed of the first material comprising a NiTi based alloy and an intermediate surface layer (48) formed of the mixture of said first material and said second material; and

3) Chandrasekaran discloses a composite guidewire wherein the weight ratio of the first to second material in the mixture capable of being in the range of 1:9 to 9:1 and more specifically in the range of 3:7 to 7:3 because this ratio is inherently dependent upon material selection (as cited by Applicant, see Specification at least page 8 lines 1-4).

12. In regards to Applicant's arguments with respect to independent claim 8, the Examiner notes in response to

4) Chandrasekaran discloses a composite guidewire wherein said intermediate portion comprises: the center layer (34,60,78) formed of the first material comprising a NiTi based alloy and an intermediate surface layer (48) formed of the mixture of said first material and said second material; and

5) and 6) Chandrasekaran discloses a composite guidewire wherein the mixture is decreased in the content of said first material toward said surface layer and increased in the content of said second material toward said surface layer such that a

compositional gradually increasing gradient is formed in a radial direction (column 2 line 59 – column 3 line 2 and column 4 line 66 – column 5 line 10).

13. In regards to Applicant's arguments with respect to independent claim 9, the Examiner notes in response to

14. 7) Chandrasekaran discloses a composite guidewire wherein said main body portion has a structure in which said center layer, said intermediate layer, said surface layer are structurally disposed in this order from a center of said main body portion toward an exterior of said main body portion (as best seen in Figure 5) (column 2 line 59 – column 3 line 2), and for completeness reiterates the paragraphs 10 and 11 as set forth above in response.

15. In regards to Applicant's arguments with respect to claims 13 and 14 and in response to applicant's argument that Chandrasekaran fails to disclose or suggest formation of the central shaft by sintering, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Claims 13 and 14 merely recite a process by which the guidewire is intended to be made and/or steps for "forming" the guidewire and do not set forth structural differences. In this case Chandrasekaran discloses a guidewire that is capable of being formed by a sintered body, said sintered body having said center layer, said surface layer, and said



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intermediate layer, wherein said center layer is capable of being formed by sintering a powder of said first material, said surface layer is capable of being formed by sintering a powder of said second material, and said intermediate layer is capable of being formed by sintering a powder of said mixture of said first material powder and said second material powder.

### ***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736